

(v) A statement indicating that the agent is not for human use.

(b) Etiologic agents assigned to biosafety level 1, 2, or 3, approved for shipment, and properly labeled and packaged may be shipped by commercial cargo carriers.

(c) All etiologic agents assigned to BL-4 or USDA-restricted animal pathogens approved for shipment and properly packaged, will be accompanied by a designated courier, or under close supervision of a responsible party who will monitor aspects of the shipment, ensuring that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.

§ 627.37 Importation directives.

Importation of etiologic agents is subject to the Public Health Service Foreign Quarantine Regulations (42 CFR 71.156). Examples of permits authorizing the importation or receipt of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§ 627.38 Shipment directives.

Shipping unmarked and unidentified etiologic agents is prohibited. Etiologic agents will be packaged, labeled, and shipped according to the requirements found in the Interstate Shipment of Etiologic Agents Regulations (42 CFR part 72) and its amendments. The USDA regulations in 9 CFR parts 102 through 104, 122 and the FDA regulations in 21 CFR parts 312 and 600 through 680 will also be followed as applicable. Packaging and labeling requirements for interstate shipment of etiologic agents are summarized and illustrated in appendix D. Permits authorizing the shipment of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§ 627.39 Transportation directives.

The packaging and labeling requirements cited above must be followed for the local transport of etiologic agents and diagnostic specimens by courier or by other delivery services. Similar requirements and restrictions applicable

to the transport of etiologic agents, diagnostic specimens, and biological products by all modes of transportation (that is, air, motor, rail, and water) are imposed by the Department of Transportation (49 CFR part 173), IATA "Dangerous Goods Regulations," the Air Transport Association "Restricted Articles Tariff 6-D," the International Civil Aviation Organization (ICAO), Postal Bulletin No. 21246 "International Mail-Hazardous Materials," 39 CFR, and, the Domestic Mail Manual. When shipments exceed 4 liters, the requirements found in AR 740-32 will be followed.

§ 627.40 Additional requirements.

Additional requirements for importation, shipment, and transportation of infectious agents and hazardous materials that must be followed are contained in the following directives:

(a) AR 40-12, Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces.

(b) AR 70-65, Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities.

§ 627.41 Sources for further information on shipment of etiologic agents.

(a) Guide for Transportation of Hazardous Materials, Vol. 4(1), February 10, 1975. Copies are obtainable from the Office of Research Grants Inquiries, NIH, Department of Health and Human Services, 5333 Westbard Avenue, Bethesda, MD 20205.

(b) The CDC, Office of Biosafety, 1600 Clifton Road N.E., Atlanta, Georgia 30333. Telephone (404) 639-3883, or FTS: 236-3883.

(c) The American Type Culture Collection (ATCC), Packaging and Shipping of Biological Materials at ATCC. Copies may be obtained from the ATCC, 12301 Parklawn Drive, Rockville, MD 20852. Phone (301) 881-2600.

(d) National Committee for Clinical Laboratory Standards (NCCLS), Procedures for the Domestic Handling and Transport of Diagnostic Specimens and

Etiologic Agents, (H5-A2), Second edition. Vol. 5, No. 1. Copies are obtainable from the NCCLS, 771 East Lancaster Avenue, Villanova, PA 19085.

Subpart G—Facilities

§ 627.42 Introduction.

The design of the facility is important in providing a secondary barrier to protect individuals inside and outside the facility. Because the hazards presented by various organisms and materials vary, the requirements for the facility will vary accordingly. The minimum facility requirements for the various biosafety levels and toxins are described below. The biosafety levels correspond to those described in the HHS Publication Biosafety in Microbiological and Biomedical Laboratories (HHS No. (NIH) 88-8395), while the large-scale biosafety levels were adapted from those described in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

§ 627.43 Biosafety level 1.

(a) *Laboratories.* Each laboratory used for this level will, as a minimum, have the following features:

- (1) A sink for handwashing.
- (2) Work surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- (3) Fly screens on any windows that can be opened.
- (4) Furnishings and surfaces that are sturdy and designed to be easily cleaned.
- (5) Spaces between furnishings and equipment that are accessible for cleaning.

(b) *Animal facilities.* Each room will have the following features:

- (1) Design and construction to facilitate cleaning and housekeeping.
- (2) A sink for handwashing within the facility.
- (3) Fly screens on any windows that can be opened.
- (4) Ventilation designed so that the direction of airflow in the animal facility is inward, with the exhausted air discharged to the outside without being recirculated.
- (5) Self-closing doors that open inward.

§ 627.44 Biosafety level 2.

(a) *Laboratories.* Each laboratory used for this level of hazard will have, in addition to the requirements stated in § 627.43(a), the following:

- (1) An autoclave available.
- (2) Containment equipment necessary for the operations unless the safety officer approves the use of a compensatory level of personal protective equipment.
- (3) An eyewash available near the laboratory.

(b) *Animal facilities.* In addition to the requirements stated in § 627.43(b), facilities will include—

- (1) A sink for handwashing in each room where animals are housed.
- (2) An autoclave available in the building.
- (3) Appropriate containment equipment unless the safety officer approves the use of a compensatory level of personal protective equipment.

§ 627.45 Biosafety level 3.

(a) *General requirements.* Each suite used as a laboratory or in which infected animals are housed will, as a minimum, have the following features:

- (1) Physical separation from areas which are open to unrestricted traffic.
- (2) All entrances to each laboratory or animal room from the nonlaboratory access corridors will be through two sets of doors. A change room or airlock may be incorporated between the doors.
- (3) The interior surfaces of walls, floors, and ceilings will be water resistant so that they may be easily cleaned.
- (4) All penetrations into the walls, floors, and ceilings should be sealed or capable of being sealed to facilitate decontamination.

(5) A foot, elbow, or automatically operated sink will be located near the exit door to each laboratory or animal room.

(6) An autoclave should be in each laboratory or animal room and will be available to the facility.

- (7) A ventilation system that will—
 - (i) Create directional airflow that draws air into the laboratory through the entry areas.
 - (ii) Not recirculate laboratory air.